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Dated: 10/10/03

Signature: 

(Ginny Blundell)

Docket No.: CIBT-P03-130  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Huston et al.

Application No.: Not Yet Assigned

Confirmation No.:

Filed: October 10, 2003

Art Unit: N/A

For: BIOSYNTHETIC BINDING PROTEINS FOR  
IMMUNO-TARGETING

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement accompanies the new patent application submitted herewith.

Those patent(s) or publications(s) in the attached from Form PTO-1449 are not supplied because they were previously cited by or submitted to the Office in a prior application number 09/325602, filed June 3, 1999 and relied upon in this application for an earlier filing date under 35 U.S.C. 120.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this


Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. CIBT-P03-130. A duplicate copy of this paper is enclosed.

Dated: October 10, 2003

Respectfully submitted,

By 

Melissa S. Rones, Ph.D.

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**Notice of References Cited**

Application/Control No.

09/558,741

Applicant(s)/Patent Under  
Reexamination  
HUSTON ET AL.

Examiner

Larry R. Helms

Art Unit

1642

Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number	Date	Name	Classification	
		Country Code-Number-Kind Code	MM-YYYY			
	A	US-6,207,804	03-2001	Huston et al	--	--
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

**FOREIGN PATENT DOCUMENTS**

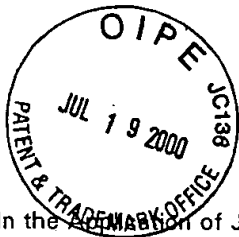
*		Document Number	Date	Country	Name	Classification	
		Country Code-Number-Kind Code	MM-YYYY				
	N						
	O						
	P						
	Q						
	R						
	S						
	T						

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Klausner, BioTechnology 4:1041 and 1043, 12/86
	V	Rudikoff et al., Proc. Natl. Acad. Sci. USA 79:1979-83, 1982
	W	Pastan et al., Celi 47:641-648, 12/86
	X	Jones et al., Nature 321:522-25, 5/86

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231



FORM PTO-1449 (Modified)  
LIST OF PATENTS AND PUBLICATIONS  
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)  
Sheet 1 of 1

In the name of James S. HUSTON, et al.

Serial No.: 09/558,741

Art Unit: 1644

Filed: April 26, 2000

Examiner: T. Cunningham

Title: BIOSYNTHETIC BINDING PROTEINS FOR IMMUNO-TARGETING

ATTACH  
TO  
#4

U.S. PATENT DOCUMENTS

Exam. Init.	Ref. Desig.	Document No.	Date	Name	Class	Sub Class	Filing Date
LA	AA-1	5,877,305	March 2, 1999	Huston et al.	—		
LA	AB-1	6,054,561	April 25, 2000	Ring	—		

FOREIGN PATENT DOCUMENTS

Exam. Init.	Ref. Desig.	Document No.	Publication Date	Country or Patent Office	Class	Sub Class	Translation YES NO
	AC-1						

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

Exam. Init.	Ref. Desig.	Description
	AD-1	

Examiner:

Date Considered:

11/6/9

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RM PTO-1449

## FORMATION DISCLOSURE STATEMENT

ATTY DOCKET NO.: PP0926.105

APPLICANT: Huston et al.

Serial No.: 09/558,741

FILING DATE: 4/26/00

GROUP: unassigned

## U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AG	5,258,498	11/02/93	Huston et al.	530	350	
	AH	5,260,203	11/09/93	Ladner et al.	435	172.3	
	AI	5,571,894	11/05/96	Wels et al.			
	AJ	5,587,458	12/24/96	King et al.			

## FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.		FILING DATE:	GROUP:
	CCCC	Houston, Abstract from NIH Grant, Serial No. U01 CA51880-05.	
	CCCD	Pluckthun (1992) "Mono- and Bivalent Antibody Fragments Produced in Escherichia coli: Engineering, Folding and Antigen Binding," <u>Immunological Reviews</u> , 130: 151-188.	
EXAMINER		DATE CONSIDERED	

FORM PTO-1449

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APPLICANT: Huston et al.

Serial No.: 09/558,741

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FILING DATE: 4/26/00

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CCQ	Wels et al. (1992) Cancer Research, Vol. 52, pp. 6310-6317, "Selective Inhibition of Tumor Cell Growth by a Recombinant Single-Chain Antibody Toxin Specific for the erbB-2 Receptor"
CCR	Nedelman et al. (1993) The Journal of Nuclear Medicine, Vol. 34, pp. 234-241, "Rapid Infarct Imaging with a Technitium-99m-Labeled Anti-myosin Recombinant Single-Chain Fv: Evaluation in a Canine Model of Acute Myocardial Infarction"
CCS	Adams et al. (1993) Abstract, International Conference on Monoclonal Antibody Immunoconjugates for Cancer, "Demonstration of in vivo specificity of 125I-741F8 sFv, a single-chain Fv molecule"
CCT	Huston et al. (1993) Immunotechnology, Proceedings of the 21st Federal of European Biochemical Societies Meeting, Dublin, pp. 47-60, "Single-chain immunotechnology of Fv analogues and fusion proteins"
CCU	McCartney et al. (1993) Biotechnology, Advances in Gene Technology Protein Engineering and Beyond, Proceedings of the 1993 Miami Bio/Technology Winter Symposium, "Refolding of Single-Chain Fv with c-Terminal Cysteine (sFv'): Formation of Disulfide-Bonded Homodimers of Anti-c-erbB-2 and Anti-digoxin sFv'"
CCV	Huston et al. (1993) Intern. Rev. Immunol., Vol. 10, pp. 195-217, "Medical Applications of Single-Chain Antibodies"
CCW	Adams et al. (May 1993) Abstract, The Tenth International Hammersmith Conference, "Demonstration of in vivo tumor specificity of monovalent and divalent forms of 125I-741F8 sFv, an anti-c-erbB-2 single-chain Fv molecule"
CCX	Huston et al. (May 1993) Abstract for the 10th Hammersmith Meeting "Refolding and Characterization of single-chain Fv analogues having C-terminal cysteine (sFv): physicochemical behavior in vitro and tumor localization in vivo of monovalent sFv and bivalent (sFv) <sub>2</sub> species directed to the c-erbB-2 tumor antigen and digoxin"
CCY	Holliger et al. (1993) Proc. Natl. Acad. Sci. USA, Vol. 90, pp. 6444-6448, "Diabodies: Small bivalent and bispecific antibody fragments"
CCZ	Adams et al. (1993) Cancer Research, Vol. 53, pp. 4026-4034, "Highly Specific in Vivo Targeting by Monovalent and Divalent Forms of 741F8 Anti-c-erbB-2 Single-Chain Fv'"
CCCA	Jacobs (1991) Biotechnology 9:258-262.
CCCB	Reichmann et al. (1988) Nature 332: 323-327.

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	CCE	Whitlow et al. (1991), Methods: A Companion to Methods in Enzymology, Vol. 2, No. 2, pp. 97-105, "Single-Chain Fv Proteins and Their Fusion Proteins"
	CCF	Nedelman et al. (1991) Abstract Form for Scientific Papers, No. 32070 The Society of Nuclear Medicine 38th Annual Meeting, "Rapid Infarct Imaging with a New Tc-99m Antimyosin sFv Fragment: Evaluation in Acute Myocardial Infarction in Dogs"
	CCG	Waldmann (1991) Science, Vol. 252, pp. 1657-1662, "Monoclonal Antibodies in Diagnosis and Therapy"
	CCH	Clackson et al. (1991) Nature, Vol. 352, pp. 624-628, "Making antibody fragments using phage display libraries"
	CCI	Ring et al. (1991) Molecular Immunology, Vol. 28, No. 8, pp. 915-917, "Identity of BCA200 and c-erbB-2 Indicated by Reactivity of Monoclonal Antibodies with Recombinant c-erbB-2"
	CCJ	Hilenic et al. (1991) Cancer Research, Vol. 51, pp. 6363-6371, "Construction, Binding Properties, Metabolism, and Tumopr Targeting of a Single-Chain Fv Derived from the Pancarcinoma Monoclonal Antibody CC49"
	CCK	Wels et al. (1992) J. Steroid Biochem. Molec. Biol., Vol. 43, No. 1-3, pp. 1-7, "Diminution of Antibodies Directed Against Tumor Cell Surface Epitopes: A Single Chain Fv Fusion Molecule Specifically Recognizes the Extracellular Domain of the c-erbB-2 Receptor"
	CCL	Pack et al. (1992) Biochemistry, Vol. 31, No. 6, pp. 1579-1584, "Miniantibodies: Use of Amphipathic Helices To Produce Functional, Flexibility Linked Dimeric Fv Fragments with High Avidity in Escherichia coli"
	CCH	Yokota et al. (1992) Cancer Research, Vol. 52, pp. 3402-3408, "Rapid Tumor Penetration of a Single-Chain Fv and Comparison with Other Immunoglobulin Forms"
	CCN	Cumber et al. (1992) The Journal of Immunology, Vol. 149, No. 1, pp. 120-126, "Comparative Stabilities in Vitro and in Vivo of a Recombinant Mouse Antibody FvCys Fragment and a bisFvCys Conjugate"
	CCO	Wels et al. (1992) Biotechnology, Vol. 10, pp. 1128-1132, "Construction, Bacterial Expression and Characterization of a Bifunctional Single-Chain Antibody-Phosphatase Fusion Protein Targeted to the Human ERBB-2 Receptor"
	CCP	Schott et al. (1992) Cancer Research, Vol. 52, pp. 6413-6417, "Differential Metabolic Patterns of Iodinated versus Radiometal Chelated Anticarcinoma Single-Chain Fv Molecules"

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INFORMATION DISCLOSURE STATEMENT		APPLICANT: Huston et al.	
		Serial No.: 09/558,741	
EXAM. INIT.		FILING DATE: 4/26/00	GROUP: unassigned
	CR	Ring et al. (1989) Cancer Research Vol. 49, No. 11, pp. 3070-3080, "Distribution and Physical Properties of BCA200, a M <sub>200,000</sub> Glycoprotein Selectively Associated with Human Breast Cancer"	
	CS	Dillman (1989), Annals of Internal Medicine, Vol. 111, pp. 592-603, "Monoclonal Antibodies for Treating Cancer"	
	CT	Glockshuber et al. (1990) Biochemistry, Vol. 29, pp. 1362-1367, "A Comparison of Strategies to Stabilize Immunoglobulin F <sub>v</sub> Fragments"	
	CU	Queen et al. (1989) Proc. Natl. Acad. Sci., Vol. 86, pp. 10029-10033, "A humanized antibody that binds to the interleukin 2 receptor"	
	CV	Hird et al. (1990) Genes and Cancer, pp. 183-189, "Immunotherapy with Monoclonal Antibodies"	
	CV	Batra et al. (1990) The Journal of Biological Chemistry, Vol. 265, No. 25, pp. 15198-15202, "Anti-Tac(Fv)-PE40, a Single Chain Antibody Pseudomonas Fusion Protein Directed at Interleukin 2 Receptor Bearing Cells"	
	CX	McGuire et al. (1990) Journal of the National Cancer Institute, Vol. 82 No. 12, pp. 1006-1015, "How to Use Prognostic Factors in Axillary Node-Negative Breast Cancer Patients"	
	CY	Shealy et al. (1990) The Journal of Nuclear Medicine, Vol. 31, No. 5, Abstract Book Proceedings of the 37th Annual Meeting, "Characterization and Biodistribution of Tc-99m Labeled Single Chain Antibody Fv Fragment (sFv)"	
	CZ	Colcher et al. (1990) J. Natl. Cancer Inst., Vol. 82, No. 14, pp. 1192-1197, "In Vivo Tumor Targeting of a Recombinant Single-Chain Antigen-Binding Protein"	
	CCA	Batra et al. (1990) Biochemical and Biophysical Research Communications Vol. 171, No. 1, pp. 1-6, "TGFA-anti-Tac(Fv)-PE40: A Bifunctional Toxin Cytotoxic for Cells with EGF or IL2 Receptors"	
	CCB	Tai et al. (1990) Biochemistry, Vol. 29, pp. 8024-8030, "A Bifunctional Fusion Protein Containing Fc-Binding Fragment of B of Staphylococcal Protein A Amino Terminal to Antidigoxin Single-Chain Fv"	
	CCC	Huston et al. (1990) Bispecific Antibodies and Targeted Cellular Cytotoxicity, Second International Conference, pp. 201-206, "Bifunctional Single-Chain Fv Fusion Proteins"	
	CCD	Huston et al. (1990) Academic Press, Inc., Methods in Enzymology, Vol. 203, pp. 46-89, "Protein Engineering of Single-Chain Fv Analogs and Fusion Proteins"	
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FORM PTO-1449

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APPLICANT: Huston et al.

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GROUP: unassigned

CE	Bjorn et al. (1985) Cancer Research, Vol. 45, pp. 1214-1221, "Evaluation of Monocolonal Antibodies for the Development of Breast Cancer Immunotoxins"
CF	Fisher et al. (1986) Journal of Clinical Oncology. Vol. 4, No. 6, pp. 929-941, "Ten-Year Results From the National Surgical Adjuvant Breast and Bowel Project (NSABP) Clinical Trial Evaluating the Use of L-Phenylalanine Mustard (L-PAH) in the Management of Primary Breast Cancer"
CG	Satow et al. (1986) J. Mol. Biol., Vol. 190, pp. 593-604, "Phosphocholine Binding Immunoglobulin Fab McPC603 An X-ray Diffraction Study at 2.7 Å"
CH	Amit et al. (1986) Science, Vol. 233, pp. 747-753, "Three-Dimensional Structure of An Antigen-Antibody Complex at 2.8 Å Resolution"
CI	Sheriff et al. (1987) Proc. Natl. Acad. Sci. USA, Vol. 84, pp. 8075-8079, "Three-dimensional structure of an antibody-antigen complex"
CJ	Colman et al. (1987) Nature, Vol. 326, pp. 358-363, "Three-dimensional structure of a complex of antibody with influenza virus neuraminidase"
CK	Bartlet et al. (1987) The Lancet, Vol. II, No. 8552, pp. 171-175, "Adjuvant Tamoxifen in the Management of Operable Breast Cancer: The Scottish Trial"
CL	Aisner et al., (1987) Journal of Clinical Oncology, Vol. 5, No. 10, pp. 1523-1533, "Chemotherapy Versus Chemoimmunotherapy (CAF v CAFVP v CMF Each ± HER) for Metastatic Carcinoma of the Breast : A CALGB Study"
CM	Huston et al. (1988) Proc. Natl. Acad. Sci., Vol. 85, pp. 5879-5883, "Protein engineering of antibody binding sites: Recovery of specific activity in an anti-digoxin single-chain Fv analogue produced in Escherichia coli"
CN	Sefton (1988) Trends in Genetics, Vol. 4, No. 9, pp. 247-248, "news about c-erb-B-2 and HER2"
CO	Bird, et al. (1988) Science, Vol. 242, pp. 423-426, "Single-Chain Antigen-Binding Proteins"
CP	Vogel et al. (1988) Biochemistry, Vol. 28, pp. 2961-2966, "Binding Domains and Epitopes in Platelet-Derived Growth Factor"
CQ	Orlandi et al. (1989) Proc. Natl. Acad. Sci. USA, Vol. 86, pp. 3833-3837, "Cloning immunoglobulin variable domains for expression by the polymerase chain reaction"

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FORM PTO-1449

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# INFORMATION DISCLOSURE STATEMENT

APPLICANT: Huston et al.

Serial No.: 09/558,741

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FORM PTO-1449

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## U.S. PATENT DOCUMENTS

EXAM. INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
AA	4,472,509	09/18/84	Gansow et al.	436	548	
AB	4,479,930	10/30/84	Hnatowich	424	1.1	
AC	4,753,894	06/28/88	Frankel et al.	436	548	
AD	4,946,778	08/07/90	Ladner et al.	435	69.6	
AE	5,091,513	02/25/92	Huston et al.	530	387	
AF	5,132,405	07/21/92	Huston et al.	530	387.3	

## FOREIGN PATENT DOCUMENTS

EXAM. INIT.	DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
BA	W085/03523	08/15/85	PCT					
BB	W088/09344	01/12/88	PCT					
BC	0502812 A1	09/09/92	EPO					
BD	W092/15682	09/17/92	PCT					
BE	W093/06217	04/01/93	PCT					

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	FILING DATE:	GROUP:
CA	Saul et al. (1978) The Journal of Biological Chemistry, Vol. 253, No. 2, pp. 585-597, "Preliminary Refinement and Structural Analysis of the Fab Fragment from Human Immunoglobulin New at 2.0 A Resolution"	
CB	Khaw et al. (1980) Science, Vol. 209, No. 4453, pp. 295-297, "Myocardial Infarct Imaging of Antibodies to Canine Cardiac Myosin with Indium-111-Diethylenetriamine Pentaacetic Acid"	
CC	Kunkel (1985) Proc. Natl. Acad. Sci. Vol. 82, pp. 488-492, "Rapid and efficient site-specific mutagenesis without phenotypic selection"	
CD	Chen et al. (1985) DNA, Vol. 4, No. 2, pp. 165-170, "Laboratory Methods Supercoil Sequencing: A Fast and Simple Method for Sequencing Plasmid DNA"	

EXAMINER

DATE CONSIDERED